

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of : Confirmation No. 1112
Edwin Southern : Attorney Docket No. 2004_0200
Serial No. 10/772,467 : Group Art Unit 1645
Filed February 6, 2004 : Examiner A. Marschel

ANALYZING POLYNUCLEOTIDE SEQUENCES

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BEST AVAILABLE COPY

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☐ each U.S. Patent and U.S. Patent application publication;
- ☐ each reference previously cited in the international application
PCT/_____; and/or
- ☐ each reference previously cited in prior parent application Serial No.
_____.

1a. [X] This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, or

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

and thus no certification and/or fee is required.

- 1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

- (1) ☐ the certification of paragraph 2 below is provided, **or**,
(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

- 1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

**the certification of paragraph 2 below is provided, and
the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.**

2. It is hereby certified

- a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:

- a. ☐ a full or partial English language translation submitted herewith,

- b. ☐ a foreign patent office search report (in the English language) submitted herewith,
 - c. ☐ the concise explanation contained in the specification of the present application at page,
 - d. ☐ the concise explanation set forth in the attached English language abstract,
 - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☐ A foreign patent office search report citing one or more of the references is enclosed.
6. ☐ Statement Under 37 CFR 1.704(d)

Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart application, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

7. ☒ The cited references relate to prior OGT litigations and are explained in the following memorandum.

This memorandum sets out the documents from the various pieces of litigation in which the Applicant, Oxford Gene Technology (OGT), has been involved in the US and in the UK that could bear on claim construction or validity issues and that could bear on whether or not there is an interference in fact. These documents are listed on the seventeen (17) attached PTO-1449 forms as Documents 1, 3-41 and 43-132 (Documents 2 and 42 have been deleted prior to filing as lacking relevance). The cited documents are also identified sequentially hereinbelow by the same Document No. for the Examiner's convenient reference. There are further documents from the US proceedings which are set out in the court dockets, but the Applicant does not believe that these contain argument or evidence that could be relevant. For completeness, copies of the dockets are attached as Document Nos. 133-137. There are additional expert reports not listed in the dockets, but sealed under the various protective orders in the US which the Applicant does not believe relate to these issues.

The Applicant is unable to disclose a number of pleadings and reports from these litigations. In the US a number of documents are subject to protective orders and so cannot be disclosed. Witness statements and experts reports served by a party in UK proceedings are subject to the implied undertaking that they can "only be used for the

purpose of the proceedings in which they are served” (Part 32.12 Civil Procedure Rules). Such evidence will only enter the public domain if there is a trial and the evidence contained in a particular witness statement or report is given in evidence. The Affymetrix litigation in the UK settled before the trial began and, as a result, none of the evidence was ever given. Any disclosure of evidence served by Affymetrix to the Applicant would constitute a breach of the implied undertaking and a contempt of court by the Applicant.

Documents that cannot be disclosed are shown in the list hereinbelow and lack a Document No. While the Applicant is prohibited from disclosing these documents, the Applicant believes that the documents which are disclosed in this IDS provide the same evidence and arguments relevant to the above issues. Thus the Applicant believes that confidential documents merely restate or reargue the same points or evidence raised in the documents which are disclosed.

Documents in OGT v Affymetrix UK action for infringement and revocation

There is no restriction on OGT in what it does with the evidence it served in the proceedings (other than one confidential witness statement and evidence served in reply that makes reference to Affymetrix evidence). The following documents are potentially relevant to validity of OGT’s patents and arguments/evidence on questions of density in relation to Affymetrix’s patent that could be relevant to whether there is an interference in fact.

Document No. and Document Description	Date
1. Affymetrix Opening Submission	22.03.01
UK Pleadings on Affymetrix Patent	
2. Deleted	
3. Notice to Admit Facts	28.01.00
4. Second Defendant’s Response to the Claimant’s Notice to Admit Facts dated 28.01.00.	22.06.00
5. Particulars of Independently Valid Claims	22.06.00
6. Statement of Reasons	30.06.00
7. Statement of Opposition	30.06.00
8. Re-Re-Re Amended Particulars of Objections	13.03.01
UK Pleadings on OGT Patent	
9. OGT Amended Particulars of Claim	26.11.99
10. OGT Amended Particulars of Infringement	01.09.00
11. Defence and Counterclaim	06.08.99
12. Amended Particulars of Objections	15.01.01

13. Re-re-Amended Reply and Defence to Counterclaim	02.03.00
OGT Expert Reports from UK Infringement Action	
14. Summary of Expert Report of Dr D Bentley	30.01.01
15-34. Expert Report of Dr D Bentley and Annex 1-19	
35. Expert Report of Prof. W Pfleiderer and Annex 1	19.01.01
36-38. Expert Report of Dr D Wallace Annex 1-2	18.01.01
Supplemental Expert Report of Dr D Bentley	16.03.01
Supplemental Expert Report of Prof. W Pfleiderer	09.03.01
Supplemental Expert Report of Dr D Wallace	06.03.01
Affymetrix Expert Reports from UK Infringement Action	
Expert Report of Dr J Wetmur	22.01.01
Expert Report of Dr A Cass	22.01.01
Expert Report of Dr R Gamble	21.01.01
Supplemental Expert Report of Dr J Wetmur	08.03.01
Supplemental Expert Report of Dr A Cass	15.03.01
Supplemental Expert Report of Dr R Gamble	08.03.01
OGT Witness Statements from UK Infringement Action	
39. Witness Statement of Dr Paul Hyman Silverman and Exhibit PS-1	22.11.00
40-41, 43-44. First Witness Statement of Prof E Southern and Exhibits EMS-1 to EMS-3	01.05.00
45-46. Fifth Witness Statement of Prof E Southern and Annex 4	22.01.01
47. Witness Statement of Peter Jay Coassin	22.01.01
First Confidential Witness Statement of Alan-Philippe Blanchard	19.01.01
48-54. Witness Statement of Dr Timothy Stephen Fell and Exhibits TSF-1 to TSF6	18.01.01
55. Witness Statement of Stewert Leonard Huxley	08.01.01
56. Witness Statement of Martin George Johnson	19.01.01
Sixth Witness Statement of Prof E Southern	09.03.01
Second Witness Statement of Peter Jay Coassin	09.03.01
Witness statement of Dr Uwe Maskos	13.03.01
Affymetrix Witness Statements from UK Infringement Action	
Witness Statement of Dr S Fodor	21.01.01
Witness Statement of V Norviel	10.07.00
Cited References In UK infringement/Revocation Action not cited on PTO File for '637 or '270 Patents	
57. Multi-analyte immunoassay (Elkins)	04.04.89

58. An Immobilised Enzyme Membrane Fabrication Method using an ink jet nozzle (Kimura et al.)	22.03.88
59. Strategies for epitope analysis using peptide synthesis (Geysen et al.)	00.05.87
60. Human Genome Linking with Cosmids and Yeast Artificial Chromosomes (Monaco)	29.04.89
61. GB 1,526,708 (Alfa-Laval)	27.09.78
62. US 4,689,405 (Frank)	25.08.87
63. Statutory Declaration on Presentation entitled "Synthesis of Oligonucleotides Tethered to a glass surface: Applications in the Analysis of Nucleic Acid Sequences" (Southern)	28.04.89
64. Ekins, Presentation entitled "Why we should move towards non-isotopic immunoassay?" (Ekins)	11.04.88
65. Lysov et al. <u>Doklady Biochemistry</u> , Vol. 303, 436-438 "A new method for Determining the DNA Nucleotide Sequence by Hybridisation with Oligonucleotides"	00.12.88
66. Witness statement of Prof E Southern describing a presentation given by a colleague of Aishi Wada in Japan (Wada)	00.07.87

The Affymetrix case on invalidity is set out in the Amended Particulars of Objections (Document No. 12) which was filed and in the public domain and in their Opening Submission (Document No. 1). Affymetrix's Opening Submission is now in the public domain (as it was filed with the EPO by one of the opponents to Affymetrix's patent EP 0 619 321) and provides a detailed outline of the evidence Affymetrix was relying on to attack the validity of OGT's patent.

Affymetrix served three expert reports (with supplemental reports in reply) that all contained evidence relating to the validity of OGT's patent. 0 373 203. Affymetrix also served two witness statements, but these do not contain any evidence dealing with the validity of OGT's patents. The expert reports relied on were as follows:

Dr J Wetmur (disclosure prohibited): This evidence provides an overview of the field of microarrays and then discusses the prior art cited against OGT's patent by Affymetrix. The allegations of anticipation and obviousness covered in the report are summarised in paragraphs 184 to 242 of the Affymetrix Opening Submission. Affymetrix also served a report by Dr Wetmur in the US litigation as set out below

Dr A Cass (disclosure prohibited): The report provides an opinion on the lack of enablement of OGT's patent and discusses the history of OGT's efforts to put the invention into effect (paragraphs 169-175 of the Opening Submission). It also discusses the experiment carried out by OGT as part of the proceedings (paragraphs 175 to 183 of the Opening Submission). The report also contains opinions on anticipation and obviousness as summarised in paragraphs 184 to 242 of the Affymetrix Opening Submission.

Dr R Gamble (disclosure prohibited): Gives evidence for Affymetrix as an expert familiar with pen plotters, ink-jet printers and laser typesetting on whether a person skilled in the art could have made large dense arrays using ink-jet technology from the teaching in the OGT patent. A summary of this evidence is set out in paragraphs 151 to 163 of the Affymetrix Opening Submission. This evidence covers the same ground as the declaration of Professor C Quate filed with the EPO by Affymetrix in January 1999 in opposition to OGT's patent. Professor Quate's Declaration is already of record and was cited by the Applicant in a previously filed IDS.

In addition a large amount of material has been filed with the Opposition Division of the EPO during the opposition to OGT's 0 373 203 patent. All of the relevant documents have all been filed with the USPTO. Included in those documents is the declaration of Professor C Quate which was filed with the EPO by Affymetrix in January 1999 in opposition to OGT's patent. Reference is made to this declaration in this note in relation to expert evidence on the use of on penplotters, ink jet printers and laser type setting.

There are also the following documents which were filed by OGT in the EPO opposition to Affymetrix's patent and could be relevant to arguments on questions of density in relation to Affymetrix's patent and whether there is an interference in fact.

DOCUMENTS FILED BY OGT IN OPPOSITION TO PATENT EPO 619 321	
Document No. and Document Description	
67. OGT Notice of Opposition	07.10.99
68. Statutory Declaration of E M Southern	07.10.99

Documents from the OGT v Affymetrix US Infringement Action

The following documents have been identified as potentially relevant to issues of validity:

Document No. and Document Description	Date
69. Defendant's Motion for Leave to File a Second Amended Answer	07.04.00
70. Expert Report of Dale Davis	16.08.00
71. Expert Report of Grant Morgan	17.08.00
Expert Report of Osman Basaran	18.08.00
72. Expert Report of Dr Elias James Corey	18.08.00
73. Expert Report of Dr James Wetmur	18.08.00
OGT Motion for Summary Judgment of Validity Under 35 U.S.C.	23.08.00

102 and 103	
OGT Motion for Summary Judgment of Validity Under 35 U.S.C 112, 1 st Paragraph	07.09.00
74. Affymetrix Memorandum of Points and Authorities in Support of Affymetrix's Opposition to OGT's Motion for Summary Judgment of Validity	07.09.00
75. Declaration of James G Wetmur in Support of Affymetrix's Opposition to OGT's Motion for Summary Judgment of Validity	07.09.00
76. Expert Rebuttal Report of Dr James Wetmur	08.09.00
77. Expert Report of Prof Martin Adelman	08.09.00
Expert Report Regarding Non-Enablement and Unenforceability of Dr Elias James Corey	21.09.00
OGT Reply in Support of Its Motion for Summary Judgment of Validity Under 35 U.S.C 112, 1 st Paragraph	28.09.00
78. Declaration of Dr Elias James Corey in Support of Affymetrix Opposition to OGT's Motion for Summary Judgment of Validity	21.09.00
79. Pretrial Order Exhibits 1-5, 12-13	05.10.00
Expert Report of Dr Kevin Struhl	09.10.00
80. Transcript of Markman Hearing	30.10.00
References Cited by Affymetrix in US proceedings and not cited in UK proceedings or cited on PTO File For '637 or '270 Patents	
81. Wada Abstracts of presentations given at a conference entitled "International Workshop on Automatic and High Speed – DNA – Base Sequencing" in Japan on 7-9 July 1987. (Wada)	
82. Wallace et al <u>Nucleic Acids Research</u> 6(11) 3543-3557 (1979)	
83. Uwe Maskos thesis	
84. Bannwarth, W et al., <u>DNA</u> , Volume 5, No 5 (1986), "A System for the Simultaneous Chemical Synthesis of Different DNA Fragments on Solid Support".	
85. Lohrmann et al., "New Solid Supports for DNA Synthesis", Fourth Annual Congress for Recombinant DNA Research.	
86. U.S. Patent No. 5,348,855 (Dattagupta, et al.) "Assay for Nucleic Acid Sequences in an Unpurified Sample".	
87. Goldkorn et al., <u>Nucleic Acid Research</u> , 14(22), 1986, "A simple and efficient enzymatic method for covalent attachment of DNA to cellulose. Application for hybridization – restriction analysis and for in vitro synthesis of DNA probes".	
88. Duncan et al., <u>Analytical Biochemistry</u> , 169, 104-108 (1988) "Affinity Chromatography of a Sequence – Specific DNA Binding Protein Using Teflon-Linked Oligonucleotides".	
89. Voss et al., <u>Biochemical Society Transactions</u> , 165 th Meeting, <u>London</u> , 367,368 (1987), "A simple and efficient method for covalently attaching oligonucleotides to a cellulose support matrix".	
90. Nicholls et al, <u>Journal of Clinical Laboratory Analysis</u> , 3: 122-	

135, "Nucleic Acid Analysis by Sandwich Hybridization".	
91. Wallace et al., <u>Nucleic Acids Research</u> , 9(4), 879-894, (1981) "The use of synthetic oligonucleotides as hybridization probes. II. Hybridization of oligonucleotides of mixed sequence to rabbit β -globin DNA".	
92. File History for Serial No. 07/593,589.	
93. File History for Serial No. 07/772.625.	
94. Sproat et al., <u>Nucleic Acids Research</u> , 13(8), 2979-2987 (1985), "A new linkage for solid synthesis of oligodeoxyribonucleotides"	
95. Kremsky et al., <u>Nucleic Acids Research</u> , 15(7), 2891-2909 (1987), "Immobilization of DNA via oligonucleotides containing an aldehyde or carboxylic acid group at 5' terminus".	
96. Wolf et al., <u>Nucleic Acids Research</u> , 15(7), 2911-2926 (1987), "Rapid hybridization of DNA attached to submicron latex particles".	
97. Atkinson et al., <u>Nucleic Acids Research</u> , 16(13) 6232 (1988), "A convenient procedure for the synthesis of oligodeoxyribonucleotide affinity columns for the isolation of mRNA".	
98. EPO 119 573 A1 (Johnson)	

The following experts prepared reports for Affymetrix:

Osman Basaran (filed under seal) Covers the use of ink jet printers or other print technology for the application of biological materials to a substrate. The evidence of Osman Basaran covers the same ground as the declaration of Professor C Quate filed with the EPO by Affymetrix in January 1999 in opposition to OGT's patent and the evidence given by Dr Gamble in the UK proceedings (A summary of which is set out in paragraphs 151 to 163 of the Opening Submission). Professor Quate's declaration gave evidence on penplotters, ink jet printers and laser type setting.

Dale Davis (Document No. 70 not filed under seal) This expert report relates to the question of whether OGT's '637 patent teaches one with knowledge and expertise in pen plotting to synthesize oligonucleotides.

Grant Morgan (Document No. 71 not filed under seal) This expert report relates to the question of whether OGT's '637 patent teaches one with knowledge and expertise in laser typesetting to use that technology to build precursor arrays.

Dr Elias Corey Prepared two reports. The earlier report (Document No. 72) was not filed under seal and focused on the Bannwarth (Document No. 84) and Geyson (Document No. 59) references and claims that they teach and enable every element of claim 1 of the '637 patent. The second report was filed under seal and presented Affymetrix's claims of non-enablement and of unenforceability. Affymetrix's allegations are generally set forth in its Motion for Leave to File a Second Amended Answer (Document No. 69) and the Pretrial Order (Document No. 79, Exhibits 1-5, 12-13 only). Dr. Corey criticized the experiments and conclusions reported in the '637 patent. He compared a statement in the thesis of Uwe Maskos (Document No. 83),

who was a graduate student in Prof. Southern's laboratory involved in many of the related experiments, to a statement in the '637 patent. In his thesis, Uwe Maskos stated: "After partial elution in 0.1 M NaCl no differential binding to the target was detectable, i.e. there was the same amount of binding to the shorter as to the longer oligo- t_n under these conditions, as judged by autoradiography." (p. 58) In the '637 patent, it is reported: "... differential binding to the target is detectable, i.e., less binding to the shorter than the longer oligo-dT." (Col. 9:55-57) Affymetrix argued that Prof. Southern misstated the results of this experiment. Prof. Southern explained in his deposition testimony in the Affymetrix case and in the subsequent Mergen and Motorola cases that the two descriptions were of different autoradiographs of an experiment, which were prepared for different purposes. The report by Dr. Maskos related to an autoradiograph that demonstrated the ability to synthesize oligonucleotide probes at specific locations on a glass microscope slide by showing the absence of binding of a target nucleic acid anywhere but where the oligonucleotides were synthesized. For this purpose, it was helpful to overexpose the autoradiograph. The autoradiograph described in the '637 patent, on the other hand, was obtained to determine whether differential hybridisation could be detected. For this purpose, it would be important not to overexpose the autoradiograph. Dr. Corey also criticised examples 5 and 7 of the '637 patent and conclusions in the patent, claiming that the experimental results did not support the conclusions drawn. Prof. Southern believes these criticisms are all baseless. Notably, while defendants in subsequent litigations have been aware of all of the arguments made by and on behalf of Affymetrix, they have not raised these arguments, apparently confirming Prof. Southern's position that they are baseless.

Dr K Struhl (filed under seal) The report also provides an opinion supporting Affymetrix's claims of non-enablement and of unenforceability due to inequitable conduct. The report discusses the history of OGT's efforts to put the invention into effect by a consideration of Uwe Maskos' lab notebooks and thesis. Dr. Struhl criticised examples in the '637 patent and conclusions in the patent, claiming that the notebooks and thesis show that experimental results were misrepresented and did not support the conclusions drawn. The report also discusses the Wada reference (Document No. 81) and the claim that OGT withheld material prior art from the PTO including Wada and the Maskos thesis. Affymetrix's allegations as to inequitable conduct and the withholding of references from the PTO are generally set forth on page 6 in its Motion for Leave to File a Second Amended Answer and the Pretrial Order. The "Gitschier" reference that Affymetrix alleges should have been disclosed was never properly identified by Affymetrix or relied on by any of their experts in either the US or the UK litigation. The reference appears to be based on an answer given by Professor Southern in his deposition on 23 March 2000 when asked about a reference showing use of amethylammonium chloride for hybridization when he stated "I'm sure its referenced somewhere in my writings. Gitschier I think might be one of the names". In fact the reference appears to be a paper by Wood et al (Proc. Natl. Acad. Sci. (USA) vol. 82 pp 1585-1588 (1985)) and Jane Gitschier was one of the authors. The paper has been filed with the PTO in a previous IDS.

Prof M Adelman (Document No. 77 not filed under seal) A law professor who gave evidence on Affymetrix's argument that OGT had failed to disclose the Wada conference in sufficient detail to the Examiner for the Examiner to determine whether or not it would constitute prior art.

Dr J Wetmur (Document Nos. 75-76 not filed under seal) Evidence focuses on the Dattagupta prior art reference also cited in the UK proceedings and in the EPO. The report contains similar conclusions as in the report prepared by Dr Wetmur in the UK proceedings and summarised in paragraphs 189 to 199 of the Opening Submission.

The Affymetrix Memorandum of Points and Authorities in Support of Affymetrix's Opposition to OGT's Motion for Summary Judgment of Validity (Document No. 74) was also not filed under seal and this sets out in tables the case put forward on anticipation and obviousness. The remaining documents do not disclose anything additional that would be material to the question of validity. The majority of the expert reports can be filed with the USPTO and the ones that cannot do not add anything material.

Documents from OGT v Mergen US Infringement Action

The following documents have been identified as potentially relevant to issues of validity:

Document No. and Document Description	Date
99. Technology Tutorial Transcript	18.12.03
100. OGT's Slide Presentation for Technology Tutorial	18.12.03
101. Mergen's Slide Presentation for Technology Tutorial	18.12.03
102. Clontech's Slide Presentation for Technology Tutorial	18.12.03
103. Letter from Kirkland to Perkins Coie enclosing OGT Claim Terms	30.04.04
104. Mergen Claim Terms and Proposed Construction	30.04.04
Expert Report of Kent E Vrana	12.05.04
105. Expert Report of Paul Edward Purdue	12.05.04
Expert Report of Mark Schena	03.06.04
106. Rebuttal Expert Report of Paul Purdue	04.06.04
Rebuttal Expert Report of Kent E Vrana	04.06.04
107. Mergen's Third Set of Supplemental Responses to OGT's First and Second Set of Interrogatories	17.06.04
108. OGT's Claim Construction Brief	22.07.04
109. Mergen's Opening Claim Construction Brief	22.07.04
OGT's Motion and Memorandum in Support for Partial Summary Judgment of Patent Validity and Enablement	22.07.04

Mergen's Opening Brief in Support of Motion for Summary Judgment of Invalidity of the Asserted Claims of US Patent No 6,054,270	22.07.04
Mergen's Opening Brief in Support of Motion for Summary Judgment of Invalidity of Claim 1 of United States Patent No 6,054,270 Pursuant to U.S.C. 112	22.07.04
Mergen's Answering Brief to OGT's Claim Construction Brief	05.08.04
OGT's Opposition to Mergen's Motion for Summary Judgment of Invalidity of the Asserted Claims of US Patent No. 6,054,270	05.08.04
OGT's Brief in Support of Its Motion to Strike and Opposition to Mergen's Motion for Summary Judgment of Invalidity of Claim 1 of United States Patent 6,054,270 Pursuant to 35 U.S.C. 112	05.08.04
Declaration of David B Wallace	05.08.04
Declaration of Kent E Vrana	05.08.04
Mergen Limited's Opposition to OGT Limited's Motion for Partial Summary Judgment of Patent Validity	05.08.04
110. Mergen's Reply in Support of Its Motion for Summary Judgment of Invalidity of Claim 1 of US patent No. 6,054,270 Pursuant to 35 U.S.C 112	12.08.04
111. Declaration of Norbert Stahl in Support of Mergen's Reply Brief in Support of Its Motion for Summary Judgment of Invalidity of Claim 1 of United States Patent No. 6,054,270 Pursuant to 35 U.S.C. 112	12.08.04
OGT's Reply Brief in Support of Its Motion for Partial Summary Judgment of Patent Validity	12.08.04
Mergen's Reply in Support of Its Motion for Summary Judgment of Invalidity of the Asserted Claims of US Patent No. 6,054,270	12.08.04
112. OGT's Claim Construction Brief in Response to Mergen's Claim Construction Briefing	12.08.04
113. Order and Memorandum Opinion re Claim Terms	29.09.04
114. Order and Memorandum of opinion re Expert Reports	16.11.04
115. Order and Memorandum Opinion re Summary Judgment	19.11.04
116. Mergen Limited's Motion for Reconsideration of the Court's Order Granting in Part OGT's Motion for Partial Summary Judgment of Infringement	03.12.04
117. OGT's Opposition to Mergen Limited's Motion for Reconsideration	17.12.04
118. Mergen Reply in Support of Its Motion for Reconsideration	27.12.04
119. Letter from Richard K Hermann to Judge Jordan re claims terms	07.01.05
120. Order re Mergen's Motion for Reconsideration	07.01.05

Although a lot of the documents on the Court docket (Document No. 134) were filed under seal there are sufficient documents that were not filed under seal to be able to consider Mergen's arguments on validity of the '270 patent. Mergen's Third Set of

Supplemental Responses to OGT's First and Second Set of Interrogatories (Document No. 107) was not filed under seal and contains a full summary of Mergen's arguments on claim construction and invalidity.

The litigation involved the consideration by Judge Jordan of a number of motions for validity/invalidity of the '270 patent and the exclusion of expert evidence, as well as the briefs filed by each party on the question of claim construction. The Orders and Memorandums of Opinion on claim construction (Document No. 113), the exclusion of expert evidence (Document No. 114) and motions for summary judgment (Document No. 115) provide a thorough summary of the expert evidence and submissions made by each party on the question of validity and enablement.

The Mergen expert, Dr Purdue (Document Nos. 105-106 whose report was not filed under seal) sought to establish anticipation based on the Dattagupta application '726 (Document Nos. 86 and 93) and obviousness based on the Dattagupta application '726, the Stavrianopoulos US patent 4,994,373 patent (of record), the Gingeras PCT application WO 88/01302 (of record) and the Lysov article (Document No. 65) published in 1988, which were all references cited to the US Patent Examiner during the prosecution that resulted in the '270 patent. He also relied on a Khrapko article (Document No. 121) which was published in October 1989 in FEBS Vol 256 Nos 1-2 pages 118-122. See expert report and pages 9 to 16 of Judge Jordan's Memorandum of Opinion re Expert Reports.

Mergen also relied on the expert report of Mark Schena which was sealed under the Protective Order and cannot be disclosed. However, it is a short report that contains an opinion on whether Mergen's products infringed the claims of OGT's '270 patent and does not deal with issues of validity. The report is based on the argument that the '270 patent only covers in-situ synthesis of oligonucleotides and its contents are covered in Mergen's arguments described in other documents provided, including the Court's opinions, which are attached.

Documents from OGT v TeleChem US Infringement Action

The case settled before any Markman briefs were filed or expert reports exchanged. As a result only the following document has been identified as potentially relevant to issues of validity:

Document No. and Document Description	Date
122. Telechem's Responses to OGT's First Set of Interrogatories (Nos. 1-16 [sic])	01.10.04

Telechem's Responses to OGT's First Set of Interrogatories contain TeleChem's case on invalidity for lack of enablement, anticipation and obviousness including four references

(See Response 3 on pages 7 to 9). The only reference not cited to the US Patent Examiner on the '270 and '637 files is R Polsky-Cynkin et al "Use of DNA Immobilized on Plastic and Agarose Supports to detect DNA by Sandwich Hybridization" Clinical Chemistry, Vol 31, No 9, 1438-43 (1985) (Document No. 123).

Documents from OGT v BD Clontech US Infringement Action

The case settled before any Markman briefs were filed or expert reports exchanged. The following document has been identified as potentially relevant to issues of validity:

Document	Date
Clontech Responses to Plaintiff's First Set of Interrogatories	29.08.03

The Clontech Responses to Plaintiff's First Set of Interrogatories was filed under seal. It contains Clontech's case on invalidity of OGT's '270 patent. It only refers to references that were cited during the prosecution of the '270 and '637 patents. There are arguments based on the definition of 'oligonucleotide' and 'impermeable'.

Documents from OGT v Motorola US Infringement Action

The case settled prior to the Markman hearing, but after Markman briefs had been filed. An expert report was filed by Motorola in support of its Markman Brief. The following documents have been identified as potentially relevant to issues of validity:

OGT v MOTOROLA INFRINGEMENT ACTION	
Document No. and Document Description	
Motorola's Supplemental Responses to Plaintiff's First Set of Interrogatories together with chart	06.10.03
124. OGT's Markman Brief with Exhibits	03.12.03
125. Motorola's Response to Markman Brief	16.01.04
126. Motorola's Response to Markman Brief – Exhibits A-Z	
127. Motorola's Response to Markman Brief – Exhibits A(1)-G(1)	
128. Motorola's Response to Markman Brief – Exhibits 1-3	
129. OGT's Reply to Markman Brief	15.03.04
130. OGT's Reply to Markman Brief – Exhibit A Claim Chart	
131. OGT's Reply to Markman Brief – Exhibit 1-9	
132. OGT's Reply to Markman Brief – Exhibit H-R	

Motorola's Supplemental Responses to Plaintiff's First Set of Interrogatories were subject to the Protective Order as the document contains details of entities to whom Motorola had offered to sell the e-Sensor product claimed by OGT to infringe the '270 patent. The pleading also includes a lengthy list of references (over 80 references are included without any explanation as to why those patents or publications are relevant) included as "considered by Motorola as prior art or potential prior art with respect to the '270 patent". Most were taken from the file of the '270 patent, but the following were not:

US Patent Documents
US 4,225,575 (Piasio)
US 4,521,512 (Silman)
US 4,596,697 (de Macorio)
US 4,682,891 (de Macorio)
US 4,731,325 (Palva)
US 4,792,520 (Stambrook)
US 4,806,631 (Carrico)
US 4,886,747 (Derynck)
US 4,923,901 (Koester)
US 5,008,080 (Brown)
US 5,063,081 (Cozzette)
US 5,126,276 (Fish)
US 5,149,622 (Brown)
US 5,200,051 (Cozzette)
US 4,133,639 (Harte)
US 4,378,344 (Zahradnik)
US 4,558,013 (Marinkovich)
US 4,613,566 (Potter)
US 4,689,405 (Frank)
US 4,789,628 (Nayak)
US 4,806,546 (Carrico)
US 4,775,631 (Saman)
US 4,916,056 (Brown)
US 4,965,190 (Woo)
US 5,024,940 (Brenner)
US 5,075,077 (Durley)
US 5,132,097 (Van Deusen)
US 5,160,701 (Brown)
US 5,219,762 (Legendre)
US 5,242,797 (Hirschfield)
US 6,265,178 (Martin)
US 5,466,575 (Cozzette)
US 4,877,745 (Hayes)
PCT Publication

W089/01157 (Ekins)
Other References
Kremsky <i>et al.</i> , Nucleic Acids Research, 15, 7, 2891-2909 (1987)
Khrapko <i>et al.</i> , FEBS Letters, 256, 1-2, 118-22 (Oct 1989)
Barone <i>et al.</i> , Nucleic Acids Research, 12, 10, 4051-61 (1984)
Rosenthal <i>et al.</i> , Tetrahedron Letters, 24, 16, 1691-94 (1983)
Agarwal <i>et al.</i> , Angew. Chem. Internat. Edit., 11, 6, 451-60 (1972)
Belagaje <i>et al.</i> , Nucleic Acids Research, 8, 22, 5193-5205 (1980)
Djurhuus Matthes <i>et al.</i> , Meth. Enzym, 154, 250-87 (1987)
Caruthers <i>et al.</i> , Meth. Enzym. 154, 287-313 (1987)
Horvath <i>et al.</i> , Meth. Enzym, 154, 314-326 (1987)

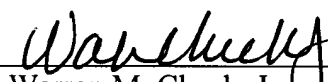
The pleading also includes a table setting out specific references from patents US 4,789,628 (Nayak), US 5,164,319 (Hafeman), US 4,994,373 (Stravianopoulos), US 4,558,013 (Marinkovich), US 4,133,639 (Harte), US 5,126,276 (Fish) and W089/01157 (Ekins) claiming that they anticipated claims 9 and 10 of the '270 patent and/or that claims 9 and 10 were obvious in view of those references.

The Applicant believes that the relevant references from this list are already cited in this application.

Respectfully submitted,

Edwin Southern

By



Warren M. Cheek, Jr.

Registration No. 33,367

Attorney for Applicant

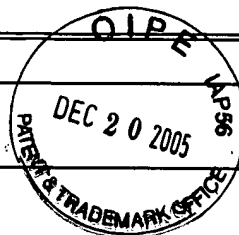
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December 20, 2005

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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	62	4,689,405	8/1987	Frank et al.			
	86	5,348,855	9/1994	Dattagupta et al.			

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	61	1 526 708	9/1978	GB			
	98	0 119 573 A1	9/1994	EP			

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	1	David Kitchin QC and Richard Meade, Affymetrix' Opening Submissions, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 02517, HC 1999 04645, pages 1-81, March 22, 2001, London, United Kingdom.
	3	Bird & Bird, Notice to Admit Facts, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case no. HC 1999 04645, pages 1-5, January 28, 2000, London, United Kingdom.
	4	Richard Meade, Bristows, Second Defendant's Response to the Claimant's Notice to Admit Facts, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case no. HC 1999 04645, pages 1-3, June 22, 2000, London, United Kingdom.
	5	Bristows, Particulars of Independently Valid Claims, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case no. HC 1999 04645, pages 1-2, June 22, 2000, London, United Kingdom.

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	6	Richard Meade, Bristows, Statement of Reasons, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case no. HC 1999 04645, pages 1-4, June 30, 2000, London, United Kingdom.
	7	Bird & Bird, Statement of Opposition, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case no. HC 1999 04645, pages 1-5, June 30, 2000, London, United Kingdom.
	8	Bird & Bird, Re-Re-Re-Amended Particulars of Objections, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case no. HC 1999 04645, pages 1-5, March 13, 2001, London, United Kingdom.
	9	Alastair Wilson QC, Amended Particulars of Claim, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case no. HC 1999 02517, pages 1-11, November 26, 1999, Oxford, United Kingdom.
	10	Bird & Bird, Amended Particulars of Infringement, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case no. HC 1999 02517, pages 12-14, September 1, 2000, London, United Kingdom.
	11	Richard Meade, Defence and Counterclaim of the First and Second Defendants, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case no. HC 1999 02517, pages 1-6, August 6, 1999, London, United Kingdom.
	12	Richard Meade, Amended Particulars of Objections of the First and Second Defendants, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case no. HC 1999 02517, pages 21-37, January 15, 2001, London, United Kingdom.

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	14	Dr. David R. Bentley, Summary of Expert Report, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-38, January 30, 2001, London, United Kingdom.
	15	Dr. David R. Bentley, Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1A-1F, pages 1-124, January 30, 2001, London, United Kingdom.
	16	Dr. David R. Bentley, Annex 1 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-17, January 30, 2001, London, United Kingdom.
	17	Dr. David R. Bentley, Annex 2 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-2, January 30, 2001, London, United Kingdom.

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	19	Dr. David R. Bentley, Annex 4 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-4, January 30, 2001, London, United Kingdom.
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	21	Dr. David R. Bentley, Annex 6 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-8, January 30, 2001, London, United Kingdom.
	22	Dr. David R. Bentley, Annex 7 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-2, January 30, 2001, London, United Kingdom.
	23	Dr. David R. Bentley, Annex 8 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-6, January 30, 2001, London, United Kingdom.

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	25	Dr. David R. Bentley, Annex 10 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-14, January 30, 2001, London, United Kingdom.
	26	Dr. David R. Bentley, Annex 11 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-5, January 30, 2001, London, United Kingdom.
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	28	Dr. David R. Bentley, Annex 13 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-8, January 30, 2001, London, United Kingdom.
	29	Dr. David R. Bentley, Annex 14 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-8, January 30, 2001, London, United Kingdom.
	30	Dr. David R. Bentley, Annex 15 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-4, January 30, 2001, London, United Kingdom.

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	31	Dr. David R. Bentley, Annex 16 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-38, January 30, 2001, London, United Kingdom.
	32	Dr. David R. Bentley, Annex 17 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-4, January 30, 2001, London, United Kingdom.
	33	Dr. David R. Bentley, Annex 18 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-2, January 30, 2001, London, United Kingdom.
	34	Dr. David R. Bentley, Annex 19 to Expert Report of Dr. David Bentley, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-4, January 30, 2001, London, United Kingdom.
	35	Prof. Wolfgang Pfeleiderer, Expert Report and Annex 1, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-40 and 1-2, January 19, 2001, Konstanz, Germany.
	36	Dr. David B. Wallace, Expert Report of David Bowen Wallace, P.E., PH.D., in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-55, January 18, 2001, London, United Kingdom.
	37	Dr. David B. Wallace, Annex 1 to Expert Report of David Bowen Wallace, P.E., PH.D., in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-25, January 18, 2001, London, United Kingdom.
	38	Dr. David B. Wallace, Annex 2 to Expert Report of David Bowen Wallace, P.E., PH.D., in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-24, January 18, 2001, London, United Kingdom.

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	39	Dr. Paul H. Silverman, Statement of Dr. Paul Hyman Silverman and Exhibit PS-1, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645 and HC 1999 02517, pages 1-2 and 1-8, November 22, 2000, Irvine, California.
	40	Prof. Edwin M. Southern, First Witness Statement of Edwin Mellor Southern, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645, pages 1-10, May 1, 2000, Oxford, United Kingdom.
	41	Prof. Edwin M. Southern, Exhibit EMS-1 to First Witness Statement of Edwin Mellor Southern, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645, pages 1-14, May 1, 2000, Oxford, United Kingdom.
	43	Prof. Edwin M. Southern, Exhibit EMS-2 to First Witness Statement of Edwin Mellor Southern, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645, pages 1-41, May 1, 2000, Oxford, United Kingdom.
	44	Prof. Edwin M. Southern, Exhibit EMS-3 to First Witness Statement of Edwin Mellor Southern, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645, pages 1-58, May 1, 2000, Oxford, United Kingdom.
	45	Prof. Edwin M. Southern, Fifth Witness Statement of Edwin Mellor Southern, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645, pages 1-13, January 22, 2001, Oxford, United Kingdom.
	46	Prof. Edwin M. Southern, Annex 4 to Fifth Witness Statement of Edwin Mellor Southern, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 04645, pages 1-7, January 22, 2001, Oxford, United Kingdom.

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	48	Dr. Timothy S. Fell, Witness Statement of Timothy Stephen Fell, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 02517, pages 1-11, January 18, 2001, Oxford, United Kingdom.
	49	Dr. Timothy S. Fell, Annex 1 to Witness Statement of Timothy Stephen Fell, in the United Kingdom litigation between Oxford Gene Technology (OGT) v. Affymetrix, case nos. HC 1999 02517, pages 1-5, January 18, 2001, Oxford, United Kingdom.
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	58	Kimura et al., "An Immobilized Enzyme Membrane Fabrication Method using an Ink Jet Nozzle", Biosensors, Vol. 4, pp. 41-52, 1988.
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	63	Dr. Edwin Southern, Statutory Declaration of Dr. Edwin Southern, in the Opposition Proceedings against EP No. 0 619 321, pp. 1-17, Oct. 1999, Kidlington, United Kingdom.
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